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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,481	06/20/2001	Takao Hamakubo	P21128	9557
7055	7590	05/03/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			SALVOZA, M FRANCO G	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,481

Applicant(s)

HAMAKUBO ET AL.

Examiner

M. Franco Salvoza

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HC

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Salvoza.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 29, 2004 has been entered.

Claims 1-6 and 15-28 have been amended. Claims 1-8 and 15-28 remain pending and are under consideration.

Objections

The amendment filed on October 29, 2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: adding the word "unfused" before the first reference to membrane-bound protein in the specification on page 6, between lines 9 and 10. In addition, the word "unfused" was added to modify "proteins" on Page 8 between lines 4 and 5. The word "unfused" was added to these two locations in the specification without any corresponding addition to the specification. The word "unfused" is not referred to in any way other than the mere addition of the word to the amended locations in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims, 1-6, 15-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Merely adding the word “unfused” to the specification without defining what the term means does not reasonably convey to one skilled in the relevant art the intended meaning or breadth of the term. For example, the word “unfused” could to one of ordinary skill in the art mean fused, conjugated, coupled, attached, covalently or non-covalently attached, attached to a molecule, gene, protein or moiety, or fused naturally or fused synthetically.

The mere addition of the word “unfused” without corresponding definitions made in the specification would not reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The word “fusion” to modify protein is also not so inherent in the use of baculovirus expression system that to use it in the alternative form of “unfused” would convey to one of ordinary skill the meaning of the term or that the applicant was in possession of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lanford et. al. (Journal of Virology: 1989; 63 (4): 1549-1557), Possee (Current Opinion in Biotechnology. 1997; 8: 569-572, cited previously) and in further view of Nohturfft et. al. (PNAS. 1999; 96: 11235-11240, cited previously) and Duncan et al. (Journal of Biological Chemistry 1997; 272 (19): 12778-12785, cited previously) for reasons of record.

Applicant has amended claims 1-6 and 15-28 by adding the word “unfused” to modify the kind of membrane-bound proteins that are being recovered from this method for recovering a budded baculovirus. Applicant argues that amending the claims may overcome the prior art rejection over Grabherr et. al. (Biotechniques. 1997; 22 (4): 730-735, cited previously).

Applicant’s arguments are considered but found unpersuasive. Lanford teaches the use of the baculovirus expression system to express a gene product in both fusion and nonfusion forms, or “unfused,” polypeptides. In particular, the reference points to the construction of nonfusion vectors with the initiation codon altered to prevent the synthesis of a fusion protein, see Lanford, 2nd column, p. 1555.

As the previous Office Action (a Request for Reconsideration) demonstrated, the Possee reference teaches the motivation for expressing any protein of interest within a baculovirus within the first full paragraph of the second column on page 570. Nohturfft and Duncan teach expression of the protein of interest, SREPB-2, in both the Endoplasmic Reticulum and Golgi

Art Unit: 1648

Apparatus, respectively. One of ordinary skill in the art at the time the invention was made would have combined the Lanford reference with Possee in further view of Nohturfft and Duncan to separate, i.e., recover, a budded baculovirus expressing an intracellular organelle unfused membrane-bound protein.

The combination of references teaches expression of an intracellular organelle unfused membrane-bound protein on the coat of a baculovirus.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success, according to the Lanford reference. The Lanford reference also points to a reasonable expectation of success, since the level of nonfusion proteins created by nonfusion vectors is comparable to the level of fusion proteins created by fusion vectors, see Lanford pp. 1555-1556.

In conclusion, all of the limitations required by the amended claims are expressly taught by the references, and the rejection is maintained for reasons of record.

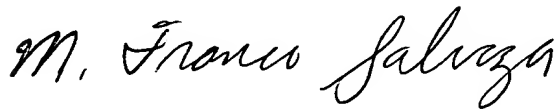
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

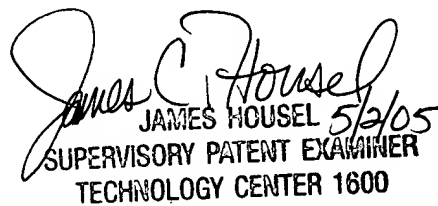
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



M. Franco Salvoza
Patent Examiner



JAMES HOUSEL 5/2/05
SUPERVISORY PATENT EXAMINER
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